

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following remarks.

I. Status of the Claims

Claims 27 and 29 are currently pending in the application. Claims 1-26, 28 and 30-45 were previously cancelled without prejudice to or disclaimer of the subject matter therein.

Claim 27 is amended to recite an isolated DNA sequence having SEQ ID NO: 10. Support for the amendment to claim 27 may be found, *inter alia*, throughout the specification and in particular in Figure 6 and in the sequence listing of the application.

Claim 29 is amended to recite a fragment of an isolated DNA sequence having SEQ ID NO: 10 comprising two GGTAGGTA sites. Support for the amendment to claim 29 may be found, *inter alia*, in paragraph [0045] bridging pages 9-10 of the specification, in Figure 6 and in SEQ ID NO: 10 of the sequence listing of the application. The two GGTAGGTA motifs are at positions 206-213 and 255-262 of SEQ ID NO: 10.

These amendments do not introduce any new matter into the application and their entry is respectfully requested.

II. The Amendments to the Specification

The specification is amended to correct obvious typographical errors between 4CL1B and 4CL3B. Support for the amendments to the specification may be found, *inter alia*, in Figure 6 and in the sequence listing of the application.

These amendments do not introduce any new matter into the application and their entry is respectfully requested.

III. The Withdrawal of Claim 27

The Office Action, at pages 2-3, withdraws claim 27 from consideration as allegedly being directed to a non-elected invention. Specifically, the Office Action alleges that claim 27, as amended, is directed to SEQ ID NO: 11, which is an invention that is independent or distinct from the originally claimed invention of SEQ ID NO: 10. Applicants respectfully traverse the withdrawal of claim 27.

Solely to advance prosecution, and not in acquiescence with the withdrawal of claim 27, the foregoing amends claim 27 to specifically recite an isolated DNA sequence having SEQ ID NO: 10. Accordingly, the invention of claim 27 is drawn to the elected invention and the withdrawal is improper. Examination on the merit of claim 27 is therefore respectfully requested.

IV. The Rejections Under 35 U.S.C. § 112, First Paragraph

1. New Matter

The Office Action, at page 4, rejects claim 29 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office Action alleges that no support could be found in the specification for the phrase “wherein said promoter region directs gene expression and includes two GGTAGGTA binding sites”. Applicants respectfully traverse this ground of rejection.

Solely to advance prosecution, and not in acquiescence with the rejection, the foregoing amends claim 29 to recite a fragment of an isolated DNA sequence having SEQ ID NO: 10 comprising two GGTAGGTA sites. As stated above, support for the amendment to claim 29 may be found, *inter alia*, in paragraph [0045] bridging pages 9-10 of the specification, in Figure

6 and in SEQ ID NO: 10 of the sequence listing of the application. The two GGTAGGTA motifs are shown at positions 206-213 and 255-262 of SEQ ID NO: 10.

Accordingly, the rejection is moot. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

2. Written Description

The Office Action, at pages 4-5, maintains the rejection of claim 29 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Office Action alleges that the specification does not disclose a representative number of promoter sequences from the 4CL genes for a representative number of gymnosperm plants and the invention as claimed is drawn to any gymnosperm 4CL promoter which comprises two GGTAGGTA binding sites. Applicants respectfully traverse this ground of rejection.

The Federal Circuit has recently clarified the law regarding written description in *Faulkner-Gunter Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006). Specifically, the court held:

- 1) examples are not necessary to support the adequacy of a written description, 2) the written description standard may be met even when actual reduction to practice is absent; and 3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.

Id., at 1366. The Federal Circuit clarified issues particularly relevant for this application. The court favorably cites *LizardTech Inc. v. Earth Resource Mapping, PTY Inc.*, 424, F.3d 1336 (Fed. Cir. 2005), explaining that the specification is written for a person skilled in the art and it is unnecessary to spell out every detail of the invention, only enough is required to convince a

person of skill in the art that the inventor possessed the invention and to enable the person to make and use the invention without undue experimentation. *Id.*

The court further clarifies, as provided in *Capon v. Eshlar*, 418 F. 3d 1349 (Fed. Cir 2005), that “the ‘written description’ requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor’s obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed.” The court also clarifies that “an actual reduction to practice is not required for written description.” *Faulkner*, at 1366. Proof of reduction to practice is not required in every case. “Thus, to the extent that written description requires a showing of “possession of the invention”, *Pfaff* makes clear that an invention can be “complete” even when an actual reduction to practice is absent.” 525 U.S. 55, 66 (1998). “The logical predicate of “possession” is, of course, “completeness.”” *Faulkner*, at 1367.

With regards to recitation of known structure, Faulkner explicitly holds: “it is the binding precedent of this court that Eli Lilly does not set forth a per se rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art.” *Id.*

In the current application, Applicants have sufficiently disclosed the invention to meet the written description requirement in line with the reasoning provided by the Federal Circuit.

Nevertheless, solely to advance prosecution, and not in acquiescence with the rejection, the foregoing amends claim 29 to recite a fragment of an isolated DNA sequence having SEQ ID NO: 10 comprising two GGTAGGTA sites. Accordingly, the claimed invention is directed to a specific 4CL promoter region that is essential for correct promoter activity.

Thus, the rejection is moot. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

3. Enablement

The Office Action, at pages 6-7, maintains the rejection of claim 29 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Office Action recognizes that the specification provides enablement for the promoter region of the 4CL gene having SEQ ID NO: 10. Nevertheless, the Office Action alleges that the claimed invention is drawn to any gymnosperm 4CL promoter comprising two GGTAGGTA binding sites for which the specification does not provide sequence information. Applicants respectfully traverse this ground of rejection.

The M.P.E.P., section § 2164.08, states the following with regard to enablement commensurate in scope with the claims:

The Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'." *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

With regard to the breadth of a claim, the M.P.E.P. states:

Atty. Dkt. No. 044463-0336
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Response to Office action dated 05-30-2007

As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. *In re Moore*, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971).

Nevertheless, solely to advance prosecution, and not in acquiescence with the rejection, the foregoing amends claim 29 to recite a fragment of an isolated DNA sequence having SEQ ID NO: 10 comprising two GGTAGGTA sites. Accordingly, the claimed invention is directed to a specific 4CL promoter region that is essential for correct promoter activity.

Thus, the rejection is moot. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

CONCLUSION

Applicants believe that all of the stated grounds of rejection have been properly traversed or rendered moot. Thus, the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date August 29, 2007

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